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Immediate Effect of Cryo-Ischemic Compression on Pain and Range of Motion in Frozen Shoulder with Active Middle Deltoid Trigger Points: A Single-Arm Pilot Study

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Abstract:

- ***Background:***

Active myofascial trigger points (MTrPs) in the shoulder girdle may add to pain and movement restriction in frozen shoulder. Cryo-ischemic compression (CIC) combines sustained manual pressure on an MTrP with simultaneous cold application. This pilot study examined the immediate effect of a single CIC session on pain and shoulder range of motion (ROM) in patients with frozen shoulder and an active middle deltoid MTrP.

- ***Methods:***

In a single-arm pre–post pilot study, 30 patients (17 men, 13 women; mean age 50.7 ± 8.2 years) received one session of CIC (mean duration 668.8 ± 151.5 s). Pain (Visual Analogue Scale, VAS, 0–10 cm) and passive goniometric abduction, external rotation and internal rotation were measured immediately before and within 5 min after treatment. Pre–post changes were analysed with the Wilcoxon signed-rank test.

- ***Results:***

Mean VAS decreased from 5.57 ± 1.63 to 1.89 ± 1.89 cm (mean change −3.68 cm; $z = -4.11$, $p < 0.001$; $r = 0.75$). Abduction increased by 5.2° (86.1° to 91.3°; $z = -4.37$, $p < 0.001$), external rotation by 3.6° (27.0° to 30.6°; $z = -4.20$, $p < 0.001$) and internal rotation by 1.9° (29.6° to 31.4°; $z = -3.06$, $p = 0.002$).

- ***Conclusion:***

A single session of CIC was followed by a large immediate reduction in pain and small gains in shoulder ROM. Without a control group, these changes cannot be attributed to CIC alone; the ROM gains are small relative to goniometric measurement error. A randomised controlled trial comparing CIC with cold application alone and ischemic compression alone, with follow-up beyond the treatment session, is warranted.

Keywords: *Bursitis; Frozen Shoulder; Trigger Points; Myofascial Pain Syndromes; Cryotherapy; Range of Motion, Articular; Physical Therapy Modalities.*

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I. INTRODUCTION

Frozen shoulder (adhesive capsulitis) is characterised by gradual onset of shoulder pain and progressive restriction of both active and passive glenohumeral motion in the absence of another identifiable intrinsic shoulder disorder.(1,2) Primary adhesive capsulitis is reported to affect 2–5.3% of the general population and occurs most often between 40 and 65 years of age.(2) Diabetes mellitus is a strong risk factor: a meta-analysis estimated the prevalence of adhesive capsulitis among people with diabetes at 13.4%, with a five-fold higher likelihood than in controls.(3) The condition substantially limits daily activities and occupational function.(2)

Histologically, the capsule and rotator interval show active fibroblastic proliferation with myofibroblast transformation and collagen deposition,(4) accompanied in some specimens by a chronic inflammatory infiltrate dominated by mast cells.(5) Contracture of the rotator interval and coracohumeral ligament reduces capsular volume and particularly restricts external rotation.(4)

A less studied contributor to pain and disability in shoulder conditions is the active myofascial trigger point (MTrP): a hyperirritable spot within a taut band of skeletal muscle that is painful on compression and can refer pain to distant sites.(6) MTrPs are highly prevalent in patients with chronic non-traumatic shoulder pain, where they were identified in every one of 72 patients examined, frequently in several shoulder girdle muscles at once, including the deltoid.(7) In a case report of adhesive capsulitis, treating MTrPs in the deltoid and neighbouring muscles was followed by rapid gains in pain-free ROM.(8) Muscle overload from sustained or repetitive low-level contraction, as may occur with compensatory movement around a stiff glenohumeral joint, is a proposed mechanism of MTrP development.(9)

Ischemic compression, the application of sustained pressure over an MTrP, produces immediate reductions in pain and trigger point sensitivity, with the effect depending on pressure and duration.(10) Cryotherapy reduces nerve conduction velocity and raises pain threshold and pain tolerance.(11) Cryo-ischemic compression (CIC) combines the two by applying cold simultaneously with sustained pressure. A combined effect is plausible, but evidence that adding cold to compression improves outcomes is limited,(12) and, to our knowledge, no study indexed in PubMed has evaluated CIC in frozen shoulder. The aim of this pilot study was therefore to estimate the immediate effect of a single CIC session on pain and shoulder ROM in patients with frozen shoulder and an active middle deltoid MTrP, and to assess the feasibility of the protocol for a future controlled trial.

II. MATERIALS AND METHODS

➢ *Study Design And Ethics*

This was a single-arm, pre–post interventional pilot study conducted at the Physiotherapy School and Centre, T.N. Medical College and B.Y.L. Nair Charitable Hospital, Mumbai, between March 2023 and December 2023. The protocol was approved by the Departmental Research Board of the Physiotherapy School and Centre, T.N. Medical College and B.Y.L. Nair Charitable Hospital. The study was not registered in a clinical trials registry. The study followed the Declaration of Helsinki, and all participants gave written informed consent before enrolment. Reporting follows the TREND statement for non-randomised evaluations.

➢ *Participants*

Thirty patients with a clinical diagnosis of frozen shoulder and an active middle deltoid MTrP were recruited from the outpatient department. Frozen shoulder was diagnosed by an orthopaedic surgeon on the basis of loss of passive external rotation of at least 50% compared with the unaffected side and normal plain radiographs. Inclusion criteria were age 18–70 years, an active MTrP in the middle deltoid identified on palpation, and no physiotherapy or interventional treatment (e.g., corticosteroid injection) for the shoulder in the preceding four weeks. An active MTrP was identified using the criteria of Simons et al.:(6) a palpable taut band, a hypersensitive spot within the band, and reproduction of the patient's familiar pain on compression.

Exclusion criteria were acute shoulder trauma or fracture, imaging-confirmed rotator cuff tear, cervical radiculopathy, peripheral vascular disease or other contraindications to cryotherapy (e.g., cold hypersensitivity, Raynaud's phenomenon), skin lesions at the treatment site, pregnancy, and systemic inflammatory arthropathy.

➢ *Intervention*

All treatments were delivered by the same trained physiotherapist. With the patient sitting, the middle deltoid MTrP was located by systematic flat palpation and the point of maximum tenderness was marked. Pressure was applied with the thumb and increased gradually until the patient reported pressure pain of approximately 7/10 on a numeric rating scale. A cold gel pack, separated from the skin by a towel, was applied over the treatment area throughout compression. Pressure was maintained, and increased as the tissue sensitivity decreased, until the patient reported a reduction in pain and the therapist perceived release of the taut band. Session duration was recorded for each patient.

➢ *Outcome Measures*

Pain intensity at rest was recorded on a 10-cm VAS anchored by "no pain" (0) and "worst possible pain" (10); the distance from the zero end was measured in centimetres. Active and passive shoulder ROM were measured with a universal long-arm goniometer by an assessor who was not involved in delivering the intervention, using standard positioning: abduction in the frontal plane, and external and internal rotation with the arm at 0° abduction. Passive ROM values are reported in this article. Goniometric shoulder measurements are highly reliable when taken by the same examiner.(13) Outcomes were measured immediately before treatment and within 5 min after treatment.

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➢ *Statistical Analysis*

As a pilot study, no formal sample size calculation was performed; 30 participants were considered sufficient to estimate the variability of outcomes for planning a future trial. Data are presented as mean ± standard deviation (SD). Because of the small sample, pre–post differences were compared with the Wilcoxon signed-rank test, and effect size was expressed as $r = |z|/\sqrt{n}$. Analyses were performed in SPSS version 26 (IBM Corp., Armonk, NY, USA), and two-tailed $p < 0.05$ was considered significant.

III. RESULTS

All 30 enrolled patients (17 men, 56.7%; 13 women, 43.3%; mean age 50.7 ± 8.2 years) completed the intervention and both assessments. The mean session duration was 668.8 ± 151.5 s (approximately 11 min). No adverse events were observed.

Pain decreased by a mean of 3.68 cm on the VAS after CIC (Table 1). All three ROM measures increased significantly: abduction by 5.2°, external rotation by 3.6° and internal rotation by 1.9°. Effect sizes were large for pain, abduction and external rotation ($r \geq 0.75$) and moderate-to-large for internal rotation ($r = 0.56$).

Table 1 Pain and Passive Range of Motion before and Immediately after Cryo-Ischemic Compression (n = 30)

Outcome	Pre, mean (SD)	Post, mean (SD)	Mean change	z	p	r
VAS pain (cm)	5.57 (1.63)	1.89 (1.89)	−3.68	−4.11	<0.001	0.75
Passive abduction (°)	86.13 (18.63)	91.33 (18.60)	+5.20	−4.37	<0.001	0.80
Passive external rotation (°)	27.03 (16.78)	30.63 (17.07)	+3.60	−4.20	<0.001	0.77
Passive internal rotation (°)	29.57 (14.68)	31.43 (13.71)	+1.86	−3.06	0.002	0.56

VAS, Visual Analogue Scale; SD, standard deviation; z and p from the Wilcoxon signed-rank test (two-tailed); $r = |z|/\sqrt{n}$.

IV. DISCUSSION

In this pilot study, a single session of CIC applied to an active middle deltoid MTrP was followed by a large immediate reduction in pain and small increases in abduction, external rotation and internal rotation in patients with frozen shoulder.

The mean VAS reduction of 3.7 cm is well above published estimates of the minimal clinically important difference for pain on a 10-cm VAS: 1.3 cm in acute pain(14) and 1.4 cm in patients with rotator cuff disease.(15) The ROM gains, by contrast, were small in absolute terms. The 1.9° gain in internal rotation in particular is unlikely to exceed goniometric measurement error, and its clinical relevance is doubtful.(13) The 5.2° gain in abduction and 3.6° gain in external rotation are statistically robust but modest; whether they reflect a real reduction in muscle guarding or measurement variability cannot be determined from this design.

Several mechanisms could explain the pain reduction. Sustained compression of an MTrP may act through segmental inhibition consistent with the gate control theory,(16) and its immediate analgesic effect depends on the pressure and duration applied.(10) The local biochemical milieu of active MTrPs contains raised concentrations of substance P, bradykinin, calcitonin gene-related peptide, serotonin and inflammatory cytokines;(17) the hypothesis that ischemia followed by reactive hyperaemia clears these substances is plausible but has not been tested directly. Cold reduces nerve conduction velocity and raises pain threshold and tolerance,(11) which may have contributed independently of the compression. Because passive ROM in frozen shoulder is limited both by capsular contracture and by pain and protective muscle guarding, reduced pain may have allowed the examiner to move the arm further before the patient guarded; a single session is unlikely to have altered the capsule itself.

An important caution is that the analgesic effect of cold alone may account for much of the observed change in pain, particularly as outcomes were measured within 5 min of an 11-min ice application. A systematic review found little evidence that adding ice to compression improves outcomes in soft-tissue injury,(12) so the claim that CIC is more effective than either component cannot be made from these data. Other myofascial approaches used for shoulder MTrPs include dry needling, which produces short-term segmental anti-nociceptive effects;(18) CIC has the practical advantages of being non-invasive and requiring only a cold pack. Myofascial treatment, if effective, would be an adjunct to, not a replacement for, established management of the capsular pathology.(19)

V. LIMITATIONS

This study has several limitations. First, without a control group, the changes cannot be attributed to CIC; placebo response, expectation, regression to the mean and the isolated effect of cold are all plausible alternative explanations. Second, outcomes were measured only immediately after a single session, so the duration of any effect is unknown. Third, participants and the treating therapist could not be blinded, and the assessor was aware that all measurements followed treatment. Fourth, the sample was small and drawn from a single centre, and the stage of frozen shoulder and diabetes status, both of which influence prognosis, were not recorded. Fifth, pressure was standardised by patient report rather than by algometry, and cold dose was not measured. Sixth, the study was not prospectively registered and was approved by a departmental research board rather than an institutional ethics committee. Finally, the subgroups of men and women

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were too small for a meaningful comparison of treatment response by sex.

Future work should be a randomised controlled trial with at least three arms (CIC, cold alone and ischemic compression alone), algometer-controlled pressure, measured skin temperature, a functional outcome such as the Shoulder Pain and Disability Index, and follow-up over several weeks of treatment. The variance estimates from this pilot can inform the sample size for such a trial.

VI. CONCLUSION

In patients with frozen shoulder and an active middle deltoid MTrP, a single session of cryo-ischemic compression was followed by a large immediate reduction in pain and small gains in shoulder ROM. These preliminary findings justify a controlled trial but do not establish the efficacy of CIC or its superiority over cold or ischemic compression alone.

DECLARATIONS

- Ethics approval and consent: The study was approved by the Departmental Research Board, Physiotherapy School and Centre, T.N. Medical College and B.Y.L. Nair Charitable Hospital, Mumbai. Written informed consent was obtained from all participants.
- Trial registration: Not registered.
- Conflict of interest: The authors declare no conflict of interest.
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- Author contributions: KT: data collection and drafting of the manuscript; CV: data analysis and interpretation; BA: supervision, guidance and critical revision of the manuscript. All authors read and approved the final manuscript.

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